

**EXHIBIT 232**

**MODEL LETTER ANNOUNCING TO THE STATE LABORATORY  
PROGRAM, AFTER A SAMPLE VALIDATION  
OR SUBSTANTIAL ALLEGATION OF NONCOMPLIANCE SURVEY,  
THAT A CLIA-EXEMPT LABORATORY DOES NOT COMPLY  
WITH APPLICABLE PROGRAM REQUIREMENTS  
(NO IMMEDIATE JEOPARDY)**

**(Date)**

Director Name  
Name of State Laboratory Program  
Address  
City, State, ZIP Code

Dear **(Director Name)**:

Re: **(Name of CLIA-Exempt Laboratory)**  
CLIA Number **(CLIA Number)**

Dear **(Director)**

Section 353(p) of the Public Health Service Act permits the Secretary to exempt a laboratory in a State that has demonstrated that its laboratory licensure laws are equal to or more stringent than Clinical Laboratory Improvement Amendments of 1988 requirements. Based on this authority, Centers for Medicare & Medicaid Services conducts sample and complaint validation surveys to ensure that CLIA requirements continue to be met by approved State licensure programs and the laboratories they license. If, in the course of such a survey, a CLIA-exempt laboratory is found to have deficiencies with respect to compliance with CLIA requirements, you are required to take appropriate enforcement action and monitor the correction of deficiencies.

A **(sample or complaint)** survey was conducted at the **(name of laboratory)** on **(date)**. CMS found that the laboratory does not comply with applicable CLIA requirements. We have enclosed a listing (Form CMS-2567, Statement of Deficiencies and Plan of Correction) of all deficiencies found by CMS surveyors during the survey.

We have informed the **(name of laboratory)** of our survey findings and that you will contact the laboratory regarding correction of the deficiencies and enforcement action. Obtain an acceptable plan of correction and forward a copy of it to us.

**(Name)**

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**(Date)**

Take appropriate enforcement action if the laboratory does not meet its plan of correction and report the enforcement action taken to us. Unless an appropriate enforcement action is taken or the deficiencies have been corrected, we may bring suit in the U.S. District Court to enjoin continuation of any activity that is causing a hazard or enjoin the continued operation of the laboratory in accordance with 42 CFR 493.1846.

Sincerely yours,

Associate Regional Administrator  
(or its equivalent)

Enclosure(s)